

9. Papers in other western states published similar articles. For example, the *Salt Lake Tribune* published a front-page article with the headline, “Deadly Diet?: With ‘Fen-Phen,’ You Might Lose More Than Pounds.”<sup>11</sup> The article noted that the Mayo Clinic announcement might cause users to reevaluate the risks and benefits of the medication.<sup>12</sup>

10. In the Northeast, numerous newspapers—in addition to the *New York Times*, with its nationwide circulation—reported the findings of the Mayo Clinic announcement.<sup>13</sup> For instance, the *Times Union* in Albany, New York, printed a story entitled “Study Links Diet Drug Combination to Heart Valve Disease” and quoted a Mayo Clinic researcher who cautioned people not to use diet drugs for cosmetic purposes; rather, the researcher recommended that only obese people with health risks should use diet

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*Purported ‘Fen-Phen’ Problems*, ORANGE COUNTY REG. (Cal.), July 10, 1997, at B01; Ed Bond, *Is Fen-Phen Too Dangerous to Prescribe?*, LOS ANGELES TIMES, July 15, 1997, at B2; *Orange County Fen-Phen Users React to the News of Possible Health Effects; People: Many Believe the Drugs Caused Dizziness or Heart Problems; Others Say the Risks of Obesity Represent the Greater Danger*, ORANGE COUNTY REG. (Cal.), July 16, 1997, at E04; Kathleen Doheny, *Diet Doctors Watching Fen-Phen; Health: Some Centers Have Abandoned the Weight-Loss Drug Combo; But at Others, It’s Merely Getting a Closer Look*, LOS ANGELES TIMES, July 16, 1997, at E1.

<sup>11</sup> *Deadly Diet?: With ‘Fen-Phen’ You Might Lose More Than Pounds*, SALT LAKE TRIB. July 9, 1997 at A1.

<sup>12</sup> *Id.*

<sup>13</sup> See, e.g., David Brown, *Doctors Report 2 Diet Drugs May Be Linked to Heart Disease*, BUFFALO NEWS, July 9, 1997, at A4; Roger Field, *Docs Link Diet Pill to Heart Ailments*, N.Y. POST, July 9, 1997, at 15; Gina Kolata, *2 Popular Diet Pills Linked to Problems with Heart Valves*, N.Y. TIMES, July 9, 1997, at A1; *‘Fen-Phen’ Suit Targets Diet Pill Combination*, BUFFALO NEWS, July 10, 1997, at A6; Sandra Boodman, *Tipping the Scale with Different Drugs*, BUFFALO NEWS, Sept. 23, 1997, at D3; *9 News at 10:00* (WWOR-TV television broadcast, July 8, 1997); *11 News at 10:00* (WPIX-TV television broadcast July 8, 1997); *4 News at 5:00* (WNBC-TV television broadcast, July 9, 1997); *7 News This Morning* (WABC-TV television broadcast, July 9, 1997).

drugs.<sup>14</sup> The Mayo Clinic announcement also was the subject of news broadcasts in New York City as well as elsewhere in the state. One New York news broadcast warned: “If you or someone you know are taking phen-fen to lose weight, this is a story you must hear. Researchers say the pills could put your health at risk.”<sup>15</sup> After a clip of a Mayo Clinic researcher, the reporter continued: “Researchers are warning people they don’t know what is worse, obesity or a drug combination used to treat it.”<sup>16</sup> New York City’s Fox News reported the heart trouble of an area woman who had open heart surgery after she took fen-phen and reported that the “Mayo Clinic and [the FDA] are warning millions of patients about taking the diet pill combination.”<sup>17</sup>

11. Another northeastern newspaper, the *Boston Herald*, printed a front-page report explaining the Mayo Clinic announcement and the possibility of “requiring warning labels on the drugs” in light of the Mayo Clinic findings.<sup>18</sup> The Mayo Clinic announcement was published in the *Boston Globe* as well as other newspapers in smaller markets around Massachusetts.<sup>19</sup>

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<sup>14</sup> Dolores Kong, *Study Links Diet Drug Combination to Heart Value Disease*, TIMES UNION (Albany, N.Y.), July 9, 1997, at A3.

<sup>15</sup> *2 News This Morning* (WCBS-TV television broadcast, July 9, 1997).

<sup>16</sup> *Id.*

<sup>17</sup> *5 News at 10:00* (WNYW-TV television broadcast, July 8, 1997).

<sup>18</sup> Michael Lasalandra, *Study Links Diet Pill Fen-Phen to Heart Problems*, BOSTON HERALD, July 9, 1997, at 01.

<sup>19</sup> See, e.g., Dolores Kong, *Blend of Diet Drugs Tied to Heart Disease*, BOSTON GLOBE, July 9, 1997, at A1; *Obesity Cure May Harm Lungs and Heart*, PATRIOT LEDGER

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12. Other examples of northeastern media coverage of the Mayo Clinic announcement appeared in the *News Journal* of Wilmington, Delaware, and *Delaware State News*. Both printed front-page stories with headlines, “Diet-Drug Combo May Be Deadly” and “Pill May Carry Extra Weight,” respectively.<sup>20</sup> The *News Journal* explained the Mayo Clinic results and the forthcoming *New England Journal of Medicine* article, and both articles addressed potential side effects of the diet drugs.<sup>21</sup>

13. In addition, the Mayo Clinic announcement was the subject of massive media attention throughout the South. For example, the Ft.

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(Quincy, Mass.), July 9, 1997, at 04; Chris Tomlinson, *Diet Drug Linked to Heart, Lung Damage*, DAILY TRANSCRIPT (Dedham, Mass.), July 9, 1997; Chris Tomlinson, *Diet Drug Linked to Heart, Lung Damage*, MIDDLESEX NEWS (Framingham, Mass.), July 9, 1997; *Diet Drug ‘Fen-Phen’ Carries Health Risks*, THE SUN (Lowell, Mass.), July 9, 1997; *Drug Combo Causes Worry*, GLOUCESTER COUNTY TIMES (Woodbury, N.J.), July 9, 1997; *Warning Issued on Diet-Drug Combination*, HARTFORD COURANT, July 9, 1997, at A4; Chris Tomlinson, *‘Fen/Phen’ Diet Pills May Be Riskier Than Obesity Condition: Researchers*, JOURNAL INQUIRER (Manchester, Conn.), July 9, 1997; Chris Tomlinson, *Government Warns of Diet-Drug Danger*, RECORD-JOURNAL (Meriden, Conn.), July 9, 1997; Judy Foreman, *Doctors Move Away from Prescribing ‘Fen-Phen’ Pairing*, BOSTON GLOBE, July 10, 1997, at B2; *Obesity-Drug Makers Sued*, PATRIOT LEDGER (Quincy, Mass.), July 10, 1997, at 04; Michael Lasalandra, *Redux Doc Defends Diet Pill*, BOSTON HERALD, July 10, 1997, at 7; Marjory Sherman, *In Fat War, Diet Pill Wins Praise*, EAGLE-TRIBUNE (Lawrence, Mass.), July 10, 1997, at A1; *FEN-PHEN: Suit Claims Risks Were Hidden*, MIDDLESEX NEWS (Framingham, Mass.), July 10, 1997; *Our Thinness Binge*, BOSTON GLOBE, July 11, 1997, at A22; Michelle Boorstein, *Possible Risks of Fen-Phen Leave Users Difficult Choice*, PATRIOT LEDGER (Quincy, Mass.); *Lessons of Fen-Phen*, REPUBLICAN-AMERICAN (Waterbury, Conn.), July 15, 1997; John MacDonald, *Hunch Leads to Diet Drug Warning*, MIDDLESEX NEWS (Framingham, Mass.), July 23, 1997; Joyce Clark, *Weight Loss Specialists Try Separating Phen from Fen*, HERALD (New Britain, Conn.), Aug. 19, 1997; Daniel Q. Haney, *U.S. Orders New Warnings Be Given for Diet Drugs*, PATRIOT LEDGER (Quincy, Mass.), August 28, 1997.

<sup>20</sup> *Diet-Drug Combo May Be Deadly*, NEWS J. (Wilmington, Del.), July 9, 1997, at A1; Kimberly Quillen, *Pill May Carry Extra Weight: ‘Fen-Phen’ May Cause Heart Problems*, DEL. STATE NEWS, July 10, 1997, at 1.

<sup>21</sup> *Diet-Drug Combo May Be Deadly*, NEWS J. (Wilmington, Del.), July 9, 1997, at A1.

Lauderdale *Sun-Sentinel* printed a front-page article providing readers with the typical symptoms of heart valve problems and recommending that patients using the medication “[d]iscuss the findings with [their] doctor[s].”<sup>22</sup> The *Tampa Tribune*, the *Orlando Sentinel*, and the *Miami Herald*, among others, published similar news reports about the Mayo Clinic’s announcement.<sup>23</sup>

14. The Georgia media published comparable stories. For instance, the *Atlanta Journal* and the *Atlanta Constitution* published articles warning about diet drugs in July 1997 and early September 1997.<sup>24</sup> One such article appearing in the *Atlanta Journal* and entitled “Researcher: Weigh Risks Before Taking ‘Phen-Fen,’” included an interview with Dr. Jack Crary, one of the physicians who participated in the Mayo Clinic research.<sup>25</sup> The possible association of valvular heart disease and diet drugs received further

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<sup>22</sup> Nancy McVicar & Glenn Singer, *Study: Diet Drugs May Be Associated With Heart Disease ‘Fen-Phen’ Could Damage Valves, Doctors Conclude*, SUN-SENTINEL (Ft. Lauderdale, Fla.), July 9, 1997, at 1A.

<sup>23</sup> See, e.g., *Drug Combo Dangerous For Dieters*, TAMPA TRIB., July 9, 1997, at 2; *Fen-Phen May Hurt Heart and Lungs: The Millions Using the Diet Drugs Should be Checked for Heart-Valve Problems, The FDA Said*, ORLANDO SENTINEL, July 9, 1997, at A1; *Fen-Phen May Hurt Heart and Lungs*, ORLANDO SENTINEL, July 9, 1997, at A1; *Warning Issued on Diet Drug*, ST. PETERSBURG TIMES, July 9, 1997, at 1A; *Drug Combo Dangerous for Dieters*, TAMPA TRIB., July 9, 1997; Dolores Kong, *Warning: Diet-Drug Mix May Damage Heart Valves*, MIAMI HERALD, July 9, 1997, A1; *Scientists: Fen-Phen is Risky*, FL. TIMES-UNION, July 9, 1997, at A1; Editorial, *Set Definite Limits on Diet Pills*, ST. PETERSBURG TIMES (Fla.), July 10, 1997, at 18A; *Drug Warnings Spur Diet Debate*, ORLANDO SENTINEL, July 13, 1997, at A4; Craig S. Palosky, *Heart Problems May Lead State to Tougher Rules for Diet Pills*, TAMPA TRIB., Aug. 2, 1997, at 1.

<sup>24</sup> See, e.g., Tomoko Hosak, *Diet Centers Watching, Waiting*, ATLANTA J., July 10, 1997, at G2; *Fen-Phen Pulled*, ATLANTA CONST., Sept. 4, 1997, at D3; *Fen-Phen Ban*, ATLANTA CONST., Sept. 10, 1997.

<sup>25</sup> See Ann Hardie, *Research: Weigh Risks Before Taking ‘Phen-Fen’: Recent Study Found Heart-Valve Problems in Users of Diet Drugs*, ATLANTA J., July 10, 1997.

attention on Georgia television stations in August 1997.<sup>26</sup> For example, both the CBS and the Fox affiliates began their nightly news programs with features on the Mayo Clinic announcement.<sup>27</sup>

15. The Mayo Clinic's announcement also was widely reported in Louisiana, including newspapers in New Orleans and Baton Rouge.<sup>28</sup> For instance, a July 9, 1997, New Orleans *Times-Picayune* article entitled "Diet Drug Combination May Be Bad For Heart" explained the chemical mechanisms of fenfluramine and vividly described the appearance of heart valve disease.<sup>29</sup> A follow-up article on July 12, 1997, cautioned readers to weigh the risks and the benefits of taking the drug.<sup>30</sup>

16. Newspapers across North Carolina—including the Raleigh-Durham-Chapel Hill area and Charlotte—also published reports about the Mayo Clinic's announcement.<sup>31</sup> For example, a July 9, 1997, article in the *Greensboro News and Record* entitled "Study Shows Diet-Drug Mix Might

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<sup>26</sup> See *Eyewitness News PrimeTime* (WAGA-TV television broadcast, Aug. 27, 1997); *WGNX News Tonight* (WGNX-TV television broadcast, Aug. 27, 1997).

<sup>27</sup> *Id.*

<sup>28</sup> See, e.g., Chris Tomlinson, *Report Says Diet Drug Combo May Damage Heart, Lungs*, BATON ROUGE ADVOC. (La.), July 9, 1997, at 4A; *The Obese Should Weigh Diet Drug Risks*, NEW ORLEANS TIMES-PICAYUNE, July 10, 1997, at A2.

<sup>29</sup> David Brown, *Diet-Drug Combination May Be Bad For Heart*, NEW ORLEANS TIMES-PICAYUNE, July 9, 1997, at A5.

<sup>30</sup> Michelle Boorstein, *Dieters Must Weigh Fen-Phen Side Effects*, NEW ORLEANS TIMES-PICAYUNE, July 12, 1997, at A13.

<sup>31</sup> *Popular Diet-Drug Mix May Damage Heart Valves*, GREENSBORO NEWS & REC. (N.C.), July 9, 1997, at A6; *Study Links Heart, Lung Ills to 'Fen-Phen' Diet Drugs; FDA Asks Doctors to Check Patients, Report Any Problems*, NEWS & OBSERVER (Raleigh, N.C.), July 9, 1997, at A4; Chris Tomlinson, *'Fen-Phen' Diet Drugs Combo Can Be Dangerous*, CHARLOTTE OBSERVER, July 9, 1997, at 6A.

Be Harmful,” reported the Mayo Clinic announcement and emphasized that the *New England Journal of Medicine*’s decision to expedite the publishing process of the Mayo Clinic findings indicated an “urgency ... which the journal and the government ... reserved for only the most serious public health matters.”<sup>32</sup>

17. The Mayo Clinic announcement received further extensive publicity in the central United States in stories appearing in a variety of major newspapers.<sup>33</sup> For instance, on July 9, 1997, three major Ohio metropolitan daily newspapers – in Cincinnati, Columbus, and Cleveland – ran stories regarding the Mayo Clinic warning.<sup>34</sup> In addition, on the same day, a San Antonio *Express-News* article entitled “FDA, Clinic Warn Diet Drug Combo Poses Serious Dangers” noted that the FDA responded to the Mayo Clinic findings by “sending letters to thousands of doctors asking them to immediately check fen-phen patients for valve problems.”<sup>35</sup> The *Dallas Morning News* printed an extensive front-page story entitled “FDA

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<sup>32</sup> *Study Shows Diet-Drug Mix Might Be Harmful*, GREENSBORO NEWS & REC. (N.C.), July 9, 1997, at A6.

<sup>33</sup> See, e.g., Leigh Hopper, *Heart-Valve Injury Seen in 24 Diet Pill Users*, AUSTIN AM.-STATESMAN, July 9, 1997, at A1; Chris Tomlinson, *Diet Drug Mix Linked to Lung, Heart Damage*, FORT WORTH STAR-TELEGRAM, July 9, 1997, at 1; Michelle Boorstein, *To Diet or Not; Fen-Phen Warning Complicates Weight-Loss Battles*, HOUSTON CHRON., July 13, 1997.

<sup>34</sup> Chris Tomlinson, *Diet Drug ‘Fen-Phen’ Dangerous, Study Says*, CLEVELAND PLAIN DEALER, July 9, 1997, at 9A; *Diet Drug Linked to Organ Damage*, CINCINNATI ENQUIRER, July 9, 1997, at A1; *Mayo Study Suggests Diet-Pill Mix May Damage Heart, Lungs*, COLUMBUS DISPATCH, July 9, 1997, at 2A.

<sup>35</sup> *FDA, Clinic Warn Diet Drug Combo Poses Serious Dangers*, SAN ANTONIO EXPRESS-NEWS, July 9, 1997, at 02A.



Warns Doctors About Diet Drug Combo; 24 Phen/Fen Users Have Same Heart Disease.” The story quoted a Texas university doctor as saying that the report changed her opinion of the drugs.<sup>36</sup> Furthermore, the story quoted a Mayo Clinic researcher as saying that this announcement shifts the risks and benefits of taking the drugs by showing increased risks for the diet drug treatment.<sup>37</sup>

### C. Publicity About Additional Reports of Heart Valve Damage

18. In late August 1997, another wave of national and local publicity accompanied the announcement that the FDA had received reports of 58 additional cases of heart valve damage allegedly attributed to diet drugs.<sup>38</sup>

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<sup>36</sup> Sue Goetinck, *FDA Warns Doctors About Diet Drug Combo 24 Phen/Fen Users Have Same Heart Disease*, DALLAS MORNING NEWS, July 9, 1997, at 1A.

<sup>37</sup> *Id.*

<sup>38</sup> *CNN Early Prime* (CNN television broadcast, Aug. 27, 1997); *CNN Headline News* (CNN television broadcast, Aug. 27, 1997); *The Cavuto Business Report* (FOX television broadcast, Aug. 27, 1997); *All Things Considered* (NPR radio broadcast, Aug. 27, 1997); *Today's Business* (CNBC television broadcast, Aug. 27, 1997); *The O'Reilly Report* (FOX television broadcast, Aug. 27, 1997); *World News This Morning* (ABC television broadcast, Aug. 28, 1997); *Early Edition* (CNN television broadcast, Aug. 28, 1997); *Fox News Now* (FOX television broadcast, Aug. 28, 1997); *Good Morning America* (ABC television broadcast, Aug. 28, 1997); *MSNBC News* (MSNBC television broadcast, Aug. 28, 1997); *CBS Morning News* (CBS television broadcast, Aug. 28, 1997); *58 More Fen-Phen Cases Cited*, HOUSTON CHRON., Aug. 28, 1997; *58 More Cases of Heart Valve Damage Linked to Diet Drugs*, DALLAS MORNING NEWS, Aug. 28, 1997, at 6A; *More Reports Link Diet Pills to Heart Valve Damage*, SAN ANTONIO NEWS-EXPRESS, Aug. 28, 1997, at 1A; Daniel Q. Haney, *Diet Drug Tied to More Problems*, BRYAN-COLLEGE STATION EAGLE, Aug. 28, 1997; Daniel Q. Haney, *58 More Heart Cases Found in Fen-Phen Users*, FORT WORTH STAR-TELEGRAM, Aug. 28, 1997, at A3; Daniel Q. Haney, *Diet Drug Linked to More Problems*, CONROE COURIER (Conroe, Tex.), Aug. 28, 1997; *More Reports Link Diet Pills to Heart Valve Damage*, SAN ANTONIO EXPRESS-NEWS, Aug. 28, 1997, at 1A 7; *News at 5:30* (KTBC-TV Aug. 28, 1997); *13 News at 5:00* (KTRK-TV Aug. 28, 1997); *13 News at 10:00* (KTRK-TV Aug. 28, 1997); *58 Cases of Fen-Phen Damage Reported to FDA*, SAN GABRIEL VALLEY TRIBUNE (Covina, Calif.), Aug. 28, 1997; *58 Cases of Fen-Phen Damage Reported to FDA*, PASADENA STAR-NEWS, Aug. 28, 1997; *58 New Heart Cases Are Believed to Be Tied to Fen-Phen Use*, CONTRA COSTA TIMES (Walnut Creek, Calif.), Aug. 28, 1997;

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*FDA Links 58 New Cases to Diet Drugs*, SAN MATEO COUNTY TIMES (San Mateo, Calif.), Aug. 28, 1997; *Fen-Phen Labels will Warn of Possible Heart Damage*, DAILY REVIEW (Hayward, Calif.), Aug. 28, 1997; *More Heart Cases Linked to Fen-Phen*, DAILY BREEZE (Torrance, Calif.), Aug. 28, 1997, at A1; *More Fen-Phen Heart Damage*, SACRAMENTO BEE, Aug. 28, 1997; *More Heart Damage Tied to 'Fen-Phen'*, ORANGE COUNTY REGISTER, Aug. 28, 1997; *Diet Drug Linked to More Ailments; Warning Ordered*, NEWS PILOT (San Pedro, Calif.), Aug. 28, 1997; Daniel Q. Haney, *More Cases of Heart Damage May Be Tied to Diet Drug*, SUN (San Bernadino, Calif.), Aug. 28, 1997, at A4; *More Damage Linked to Fen-Phen*, NORTH COUNTY TIMES (Escondido, Calif.), Aug. 28, 1997; Daniel Q. Haney, *More Heart Cases Linked to Diet Drug*, OUTLOOK (Santa Monica, Calif.), Aug. 28, 1997; Daniel Q. Haney, *Heart Damage Linked to Diet Drug*, LOS ANGELES TIMES, Aug. 28, 1997; *FDA Mandating Warnings on Diet Drugs*, SAN JOSE MERCURY NEWS, Aug. 28, 1997; *58 More 'Fen-Phen' Users Have Damaged Heart Valves*, SAN FRANCISCO EXAMINER, Aug. 28, 1997; Daniel Q. Haney, *FDA Warns of Increased Diet Pill Risk*, PRESS-ENTERPRISE (Riverside, Calif.), Aug. 28, 1997; *More Health Problems Linked to Diet Drug*, DAILY CALIFORNIAN (El Cajon, Calif.), Aug. 28, 1997; Daniel Q. Haney, *More Cases of Heart Damage Linked to Diet Drugs*, SAN DIEGO DAILY TRANSCRIPT, Aug. 28, 1997; Daniel Q. Haney, *FDA Adds Warning to Fen-Phen*, PRESS-TELEGRAM (Long Beach, Calif.), Aug. 28, 1997; *13 News at Noon* (KQVR-TV Aug. 28, 1997); *3 News at 5* (KCRA-TV Aug. 28, 1997); *KUSI Morning News* (KUSI-TV Aug. 28, 1997); *5 News This Morning* (KPIX-TV Aug. 28, 1997); Larry Tye, *FDA Requests Diet Drug Firms Issue Warnings*, BOSTON GLOBE, Aug. 28, 1997, at A1; Daniel Q. Haney, *More Heart Cases Linked to Diet Drug*, STANDARD-TIMES (New Bedford, Mass.), Aug. 28, 1997; Daniel Q. Haney, *Cases of Heart Damage Linked to Diet Drugs*, ADVOCATE (Stamford, Conn.), Aug. 28, 1997; Daniel Q. Haney, *Heart Damage Feared Linked to Diet Drugs*, GREENWICH TIME (Greenwich, Conn.), Aug. 28, 1997; *More Cases of Heart Damage Linked to Diet Drugs*, CONNECTICUT POST (Bridgeport, Conn.), Aug. 28, 1997; *More Heart Damage Linked to Diet Drugs*, NEWS-TIMES (Danbury, Conn.), Aug. 28, 1997; *More Fen-Phen Cases*, JOURNAL INQUIRER (Manchester, Conn.), Aug. 28, 1997; *Heart Damage Linked to Drug*, REPUBLICAN-AMERICAN (Waterbury, Conn.), Aug. 28, 1997, at A1; *FDA to Require Diet Drug Warning Labels*, NEW HAVEN REGISTER (New Haven, Conn.), Aug. 28, 1997; *Heart Damage Linked to Drug*, RECORD-JOURNAL (Meriden, Conn.), Aug. 28, 1997; Daniel Q. Haney, *New Warnings Required for Popular Diet Drug*, JOURNAL INQUIRER (Manchester, Conn.), Aug. 28, 1997; Daniel Q. Haney, *New Labels Ordered for Diet Pills*, HOUR (Norwalk, Conn.), Aug. 28, 1997; *FDA Orders Warning Label on Diet Drug*, PROVIDENCE JOURNAL-BULLETIN, Aug. 28, 1997; *More Heart Damage Cases Linked to Diet Drugs*, TIMES (Pawtucket, R.I.), Aug. 28, 1997; *5 News at 12:00* (WCVB-TV Aug. 28, 1997); *5 News at 5:00* (WCVB-TV Aug. 28, 1997); *5 News at 11:00* (WCVB-TV Aug. 28, 1997); *4 News at 5:00* (WBZ-TV Aug. 28, 1997); *7 News at 5:00* (WHDH-TV Aug. 28, 1997); *New England Cable News* (NECN-TV Aug. 28, 1997); *5 News Eyeopener* (WBZ-TV Aug. 29, 1997); *3 News at 5:30* (WFSB-TV Aug. 28, 1997); *More Cases of Heart Damage Reported Among Fen-Phen Users*, FLORIDA TIMES-UNION, Aug. 28, 1997; *New Heart Valve Cases Linked to Fen-Phen*, ORLANDO SENTINEL, Aug. 28, 1997, at A3; *More Heart Disease Linked to Diet Drug*, ST. PETERSBURG TIMES, Aug. 28, 1997, at 3A; *4 News at 5:00* (WFOR-TV Aug. 28, 1997); *7 News at 6:30* (WSVN-TV Aug. 28, 1997); *28 News at 5:30* (WFTS-TV Aug. 28, 1997); *10 News This Morning* (WTSP-TV Aug. 28, 1997); *10 News at Noon* (WTSP-TV Aug. 28,

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## II. **Publicity Concerning Withdrawal of Diet Drugs From the Market in September 1997**

19. When Wyeth withdrew Pondimin and Redux from the market on September 15, 1997, Wyeth issued a press release stating that the company was withdrawing the drugs based on “new, preliminary information regarding heart valve abnormalities in patients using these medications.”<sup>39</sup>

The press release detailed this new information:

On Friday afternoon, September 12, 1997, the FDA provided Wyeth-Ayerst with new summary information concerning abnormal echocardiogram findings in asymptomatic patients seen in five centers. These patients had been treated with fenfluramine or dexfenfluramine for up to 24 months, most often in combination with phentermine. Abnormal echocardiogram findings were reported in 92 of 291 subjects evaluated, including 80 reports of aortic regurgitation (mild or greater) and 23 reports of mitral regurgitation (moderate or greater).<sup>40</sup>

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1997); Daniel Q. Haney, *More Heart Damage Linked to Diet Drug*, CLEVELAND PLAIN DEALER, Aug. 28, 1997; *Evidence Mounts Against Fen-Phen*, CINCINNATI ENQUIRER, Aug. 28, 1997; *58 Cases of Heart Damage Reported*, COLUMBUS DISPATCH, Aug. 28, 1997; *More Heart Damage Tied to Diet Drug*, SPRINGFIELD NEWS-SUN (Springfield, Ohio), Aug. 28, 1997; Daniel Q. Haney, *New Heart Cases Prompt Warning*, DAYTON DAILY NEWS, Aug. 28, 1997; *Fen-Phen Warnings Ordered*, CINCINNATI POST, Aug. 28, 1997, at 1A; *More Cases of Damage to Heart Tied to Diet Drugs*, BLADE (Toledo, Ohio), Aug. 28, 1997; *Good Morning Cincinnati* KRC-TV Aug. 28, 1997; *19 News at Noon* (WOIO-TV Aug. 28, 1997; *8 Is News This Morning* (WJW-TV Aug. 28, 1997); *More Cases of Heart Damage Linked to Fen-Phen Diet Pill*, SALT LAKE TRIB., Aug. 28, 1997, at A6; *FDA Orders New Warning on Fen-Phen and Redux*, DESERET NEWS (Salt Lake City, Utah), Aug. 28, 1997.

<sup>39</sup> Press Release, Wyeth-Ayerst Laboratories, Pondimin and Redux to be Voluntarily Withdrawn (Sept. 15, 1997).

<sup>40</sup> *Id.*

The press release accordingly advised: “Patients who have used either of these products should contact their physicians.”<sup>41</sup>

20. In addition to its press release, Wyeth took out full-page advertisements in leading national and regional newspapers announcing its decision to withdraw those diet drugs from the market. The advertisements ran in approximately 150 newspapers nationwide.<sup>42</sup> These ads led with a banner in large print declaring: “An Important Message To Patients Who Have Used Pondimin or Redux.”<sup>43</sup> The ads then emphasized: “Patients who have used either Pondimin or Redux should contact their physicians.”<sup>44</sup> The ads also informed readers of new information concerning abnormal heart valve findings in individuals without symptoms who had taken Redux or Pondimin.<sup>45</sup> The advertisement provided a toll-free number for patients to use if they had any questions.

21. Wyeth also sent a “Dear Health Care Provider Letter” to approximately **450,000** doctors and pharmacists informing them of the withdrawal of the diet drugs from the market and their potential association

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<sup>41</sup> *Id.*

<sup>42</sup> See Letter from P. Wygonik to C. Greenberg, (Oct. 8, 1997) AHP-X-00050044 (listing 150 newspapers that published the advertisement).

<sup>43</sup> *An Important Message to Patients Who Have Used Pondimin or Redux* (newspaper advertising copy).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

with heart valve damage.<sup>46</sup> The letter stated that “[p]atients will be advised to contact their physicians.”<sup>47</sup>

22. The FDA issued a press release on September 15, 1997, announcing the withdrawal of Pondimin and Redux.<sup>48</sup> The FDA press release explained that the drugs were being withdrawn based on echocardiogram findings in diet drug users:

These findings indicate that approximately 30 percent of patients who were evaluated had abnormal echocardiograms, even though they had no symptoms. This is a much higher than expected percentage of abnormal test results.<sup>49</sup>

The FDA also advised that “[u]sers of these two products should contact their doctors to discuss their treatment.”<sup>50</sup>

23. Interneuron issued a press release at the time of the market withdrawal.<sup>51</sup> The press release, titled “Redux<sup>TM</sup> to Be Voluntarily Withdrawn; Pondimin Also to Be Withdrawn,” stated:

[O]n ... September 12, 1997, the FDA provided the companies with new summary information

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<sup>46</sup> Letter from Marc W. Deitch, M.D., Senior Vice President, Medical Affairs, Wyeth-Ayerst Laboratories to Healthcare Providers (Sept. 15, 1997); *see* Wyeth Press Release (stating that letter was mailed to approximately 450,000 health care providers).

<sup>47</sup> *See* Letter from Marc W. Deitch, M.D., Senior Vice President, Medical Affairs, Wyeth-Ayerst Laboratories to Healthcare Providers (Sept. 15, 1997).

<sup>48</sup> Press Release, Food and Drug Administration, FDA Announces Withdrawal of Fenfluramine and Dexfenfluramine (Sept. 15, 1997).

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> Press Release, Interneuron Pharmaceuticals, Inc., Redux to Be Voluntarily Withdrawn; Pondimin Also to Be Withdrawn (Sept. 15, 1997).

concerning abnormal echocardiogram findings in patients with no symptoms of heart valve disease. These patients had been treated with fenfluramine or dexfenfluramine for up to 24 months, most often in combination with phentermine. Redux was launched in June 1996. Abnormal echocardiogram findings were reported in 92 of 291 subjects evaluated. Two hundred and seventy-one of the 291 patients had taken fenfluramine in combination with phentermine, and 20 of the 291 had taken dexfenfluramine or a combination of dexfenfluramine and phentermine. Of these 20, six had abnormal echocardiograms, and two of the six took Redux alone ...<sup>52</sup>

Interneuron's press release also advised persons who had used the drugs to contact their physicians.

**A. National Publicity About the Market Withdrawal**

24. The press releases and Wyeth's newspaper advertisements accompanying the withdrawal of Pondimin and Redux in September 1997 led to massive publicity in both the national and local media. Reports about the withdrawal of Redux and Pondimin from the market led the major television network news broadcasts. On September 15, 1997, Tom Brokaw began the "NBC Nightly News" with an announcement about the market withdrawal and reports of heart problems:

Good evening. Two of the most popular diet drugs in America are off the market tonight, recalled by

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<sup>52</sup> *Id.* at 2.

their manufacturers after a wave of reports that they can bring on heart problems.<sup>53</sup>

Dan Rather led the “CBS Evening News” with a similar announcement:

Good evening. Two diet drugs used by millions of Americans have been withdrawn from sale nationwide. One is fenfluramine, half the diet drug combination known as fen-phen for short. It sold under the brand name Pondimin. Redux is the other drug yanked from the market. Federal health officials finally concluded that the two pills, among other things, may indeed cause heart valve damage.<sup>54</sup>

25. The following day, the national network morning shows also prominently featured the withdrawal of Pondimin and Redux and the possibility that those diet drugs could cause heart valve damage. Ann Curry on the “Today” show introduced an extensive story on these diet drugs with a blunt declaration:

A serious warning from the Food and Drug Administration. If you are using two popular diet drugs, stop. The drugs are being recalled because they could cause heart problems.<sup>55</sup>

After the news report, the “Today” show hosts continued to discuss the story with weatherman Al Roker. Roker reported that he had taken the diet drugs and lost twenty or twenty-five pounds. Katie Couric replied, “[s]o you might want to just get an echocardiogram.”<sup>56</sup>

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<sup>53</sup> *NBC Nightly News* (NBC television broadcast, Sept. 15, 1997).

<sup>54</sup> *CBS Evening News* (CBS television broadcast, Sept. 15, 1997).

<sup>55</sup> *Today* (NBC television broadcast, Sept. 16, 1997).

<sup>56</sup> *Id.*

26. The “CBS Morning News” also prominently announced the market withdrawal. Its report began with this introduction:

Millions of overweight Americans are caught in a bind this morning now that the nation’s two most popular diet drugs have been pulled from the market. Sales of Redux and fenfluramine have been linked to serious heart problems and anyone who has been taking the drugs is urged to see a doctor.<sup>57</sup>

The “CBS Morning News” continued with an interview of the acting head of the FDA, as well as with Dr. Heidi Connolly from the Mayo Clinic, about the potential association between the drugs and heart valve problems.<sup>58</sup>

27. The withdrawal and potential heart valve problems were covered just as extensively in the national print media. On September 16, 1997, *USA Today* ran a front-page story entitled “Diet Drugs Pulled Off Market.”<sup>59</sup> *USA Today* published two follow-up articles later that month on the withdrawal of Pondimin and Redux from the market.<sup>60</sup>

28. The *New York Times* likewise published a front-page story about the withdrawal on September 16, 1997, under the headline “2 Top Diet

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<sup>57</sup> *CBS Morning News* (CBS television broadcast, Sept. 16, 1997).

<sup>58</sup> *Id.*

<sup>59</sup> Nanci Hellmich and Steve Sternberg, *Diet Drugs Pulled Off Market*, USA TODAY, Sept. 16, 1997 at 1A.

<sup>60</sup> *Other Combinations Draw Interest*, USA TODAY, Sept. 22, 1997; *Withdrawal of Drugs Leaves Dieters in Quandary*, USA TODAY, Sept. 22, 1997.



Drugs Are Recalled Amid Reports of Heart Defects.”<sup>61</sup> The *New York Times* published a follow-up article the next day.<sup>62</sup>

29. The *Washington Post* also ran a front-page story about the withdrawal of Redux and Pondimin. The headline was “2 Diet Drugs Are Pulled Off Market,” and the subheading read “Health Concerns Grow After FDA Links Pills To Rare Heart Problem.”<sup>63</sup>

30. The *Wall Street Journal* reported that a Wyeth hotline had received calls from 100,000 people in three days after it had been set up and that a spokeswoman for the company had stressed the importance that people “see their doctors.”<sup>64</sup>

31. On October 8, 1997, *USA Today* ran a further story with the headline “Study Supports Diet Drug Recall” and the subheading “Early data turn up heart-valve defects.”<sup>65</sup> The article stated that after Redux and Pondimin were pulled from the market, preliminary evidence suggested that the two drugs may be “responsible for heart-valve defects.”<sup>66</sup> Another article in *USA Today* a month later provided more information about

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<sup>61</sup> Gina Kolata, *2 Top Diet Drugs Are Recalled Amid Reports of Heart Defects*, N.Y. TIMES, Sept. 16, 1997, at A1.

<sup>62</sup> Carey Goldberg, *Recall of Drugs Leaves Many Dieters Hopeless*, N.Y. TIMES, Sept. 17, 1997, at A16.

<sup>63</sup> John Schwartz, *2 Diet Drugs Are Pulled Off Market*, WASHINGTON POST, Sept. 16, 1996, at A1.

<sup>64</sup> Barbara Carton and Laura Johannes, *American Home Reports 100,000 Calls to Hot Line Since Recall of Diet Drugs*, WALL ST. J., Sept. 18, 1997.

<sup>65</sup> Nanci Hellmich, *Study Supports Diet Drug Recall*, USA TODAY, Oct. 8, 1997, at D1.

<sup>66</sup> *Id.*

possible heart valve problems. It ran under the headline “Study Supports Halting Sales of Two Diet Drugs” and declared that “[n]ew evidence from a government-funded study indicates that 25% of patients who took popular diet drugs developed heart-valve problems.”<sup>67</sup>

32. Soon after the withdrawal of the drugs, newspapers around the country began reporting about possible and pending diet drug lawsuits. For example, *The Wall Street Journal* reported that lawsuits were multiplying, fueling expectations of a lengthy, legal battle over the diet drugs and that about 100 suits already had been filed around the country.<sup>68</sup>

#### **B. Local Publicity About the Market Withdrawal**

33. The withdrawal of diet drugs from the market and possible heart problems also received similar, massive and high-profile coverage in local news media throughout the United States.

34. The market withdrawal and possible heart problems were publicized in newspapers and local news broadcasts in the West. For example, the front page of the *Los Angeles Times* included an article with the headline “2 Diet Drugs Tied to Heart Problems Taken Off the Market.”<sup>69</sup>

The caption underneath identified both fenfluramine and dexfenfluramine.

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<sup>67</sup> Nanci Hellmich, *Study Supports Halting Sales of Two Diet Drug*, USA TODAY, Nov. 12, 1997, at 20A.

<sup>68</sup> Laura Johannes and Richard B. Schmitt, *Lawyers Prepare for Deluge of Diet-Drug Suits*, WALL STREET J., Sept. 17, 1997.

<sup>69</sup> Marlene Cimon, *2 Diet Drugs Tied to Heart Problems Taken Off Market; Health: Firms Remove Fenfluramine and Dexfenfluramine Because New Evidence Raises Safety Concerns; Action Effectively Ends Fen-Phen Combination*, LOS ANGELES TIMES, Sept. 16, 1997, at A1.

The article stated the “diet drugs were removed from the market . . . after new evidence linked them to potentially serious heart valve problems, effectively ending the commonly known fen-phen combination.”<sup>70</sup> The article further provided an “800” number and a series of guidelines that instructed users to “[i]mmediately stop taking pills . . . [and] [s]ee a doctor.”<sup>71</sup> Other California newspapers ran articles echoing this advice and similarly instructing users to stop using the medications and make an appointment for an examination.<sup>72</sup> Numerous California television and radio stations broadcast similar stories.<sup>73</sup>

35. Another example of the coverage in the West appeared as a front-page story in the *Salt Lake Tribune*. The article, entitled “Diet Seller Pulls Its Diet Pills; FDA Says Review Suggests Drugs Are Not Heart Healthy,” attributed the withdrawal to abnormal echocardiogram results found in patients without symptoms of heart disease.<sup>74</sup>

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<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> See, e.g., Luran Neergaard, *FDA Health Concerns Yank Diet Drugs Off the Market*, SAN FRANCISCO EXAMINER, Sept. 16, 1997, at A7; Luran Neergaard, *Redux, Pondimin Taken Off Market After Being Linked to Heart Damage*, METROPOLITAN NEWS-ENTERPRISE, July 16, 1997; Ben Sullivan, *Recall of 2 Diet Pills Breaks Up Fen-Phen*, LOS ANGELES DAILY NEWS, Sept. 16, 1997, at N1.

<sup>73</sup> See, e.g., *2 News at 5:00* (KCBS-TV television broadcast, Sept. 15, 1997); *4 News at 5:00* (KNBC-TV television broadcast, Sept. 15, 1997); *4 News at 5:00* (KRON-TV television broadcast, Sept. 15, 1997); *5 News at 5:00* (KPIX-TV television broadcast, Sept. 15, 1997); *5 News at 11:00* (KTLA-TV television broadcast, Sept. 15, 1997); *7 News at 4:00* (KABC-TV television broadcast, Sept. 15, 1997); *7 News at 11:00* (KGO-TV television broadcast, Sept. 15, 1997); *11 News at 10:00* (KTTV-TV television broadcast, Sept. 15, 1997); *AM Drive News* (KCBS-AM radio broadcast, Sept. 15, 1997).

<sup>74</sup> Norma Wagner, *Drug Seller Pulls Its Diet Pills; FDA Says Review Suggests Drugs Are Not Heart-Healthy*, SALT LAKE TRIB., Sept. 16, 1997, at A1.

36. Local television reports also provided extensive coverage of the decision to withdraw the diet drugs from the market.<sup>75</sup> For example, one western Fox affiliate advised listeners to stop taking the medicine and consult a physician, and provided Wyeth's toll-free number.<sup>76</sup>

37. The withdrawal story also was widely reported in newspapers and on television and radio in the Northeast.<sup>77</sup> The story was prominently

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<sup>75</sup> See, e.g., *2 News at Noon* (KUTV-TV television broadcast, Sept. 15, 1997); *4 News at 5:00* (KTVX-TV television broadcast, Sept. 15, 1997); *2 News This Morning* (KUTV-TV television broadcast, Sept. 16, 1997); *4 News Good Morning Utah* (KTVX-TV television broadcast, Sept. 16, 1997); *13 News at 6:00* (KSTU-TV television broadcast, Sept. 16, 1997).

<sup>76</sup> *13 News at 12:00* (KSTU-TV television broadcast, Sept. 15, 1997).

<sup>77</sup> See, e.g., Richard A. Knox, *2 Diet Drugs Pulled as Fears Grow*, BOSTON GLOBE, Sept. 16, 1997, at A1; *Fen-Phen, Redux Off the Market*, PATRIOT LEDGER (Quincy, Mass.), Sept. 15, 1997; *Diet Drugs Recalled at FDA's Urging*, MIDDLESEX NEWS (Framingham, Mass.), Sept. 15, 1997; Lauran Neergaard, *FDA Pulls 2 Drugs for Heart Problems*, HOUR (Norwalk, Conn.), Sept. 15, 1997; *Redux, Pondimin Pulled Off Market*, TELEGRAM & GAZETTE (Worcester, Mass.), Sept. 16, 1997, at A1; Geraldine A. Collier, *Use of Redux, Pondimin Varied in Area*, TELEGRAM & GAZETTE (Worcester, Mass.), Sept. 16, 1997; Ronald Rosenberg, *Interneuron to Take Charge on Redux Loss*, BOSTON GLOBE, Sept. 16, 1997, at D1; Lauran Neergaard, *Diet Drugs Pulled From Market*, DAILY EVENING ITEM (Lynn, Mass.), Sept. 16, 1997; *Two Top Diet Pills Off the Market*, THE SUN (Lowell, Mass.), Sept. 16, 1997; Lucas Mearian, *Diet Drugs Pulled*, MIDDLESEX NEWS (Framingham, Mass.), Sept. 16, 1997, at A1; *Fen-Phen Recall Affects Thousands in Area*, THE STANDARD-TIMES (New Bedford, Mass.), Sept. 16, 1997; Lauran Neergaard, *FDA, Manufacturers Pull Popular Obesity Drugs Off Market*, SALEM EVENING NEWS (Salem, Mass.), Sept. 16, 1997; *Popular Diet Drugs Pulled From Market*, PATRIOT LEDGER (Quincy, Mass.), Sept. 16, 1997; John Schwartz, *Two Diet Drugs Removed From the Market*, HARTFORD COURANT, Sept. 16, 1997, at A1; Brigid Schulte, *Diet Drugs Pulled from Shelves by FDA*, NEWS-TIMES (Danbury, Conn.), Sept. 16, 1997; Lauran Neergaard, *FDA move Takes the Fen From Fen-Phen*, JOURNAL INQUIRER (Manchester, Conn.), Sept. 16, 1997; *2 Diet Drugs Pulled From Market*, REPUBLICAN-AMERICAN (Waterbury, Conn.), Sept. 16, 1997; Lauran Neergaard, *Diet Pills Pulled Off Shelves*, RECORD-JOURNAL (Meriden, Conn.), Sept. 16, 1997, at A16; Abram Katz, *Making Diet Drugs Continues, Despite Pull From Shelves*, HERALD (New Britain, Conn.), Sept. 16, 1997; *Diet Drugs Pulled*, GLOUCESTER COUNTY TIMES (Waterbury, Conn.), Sept. 16, 1997; Ronald Kotulak, *Two Diet Drugs Removed From Market*, ADVOCATE (Stamford, Conn.), Sept. 16, 1997; Anthony Spinelli, *Diet Drugs Pull Vanishing Act*, CONNECTICUT POST (Bridgeport, Conn.), Sept. 16, 1997, at C1-2; Raja Mishra, *2 Weight Drugs Pulled Off Market*, GREENWICH TIME (Greenwich, Conn.), Sept. 16, 1997; Abram Katz, *2 Popular Diet Drugs Yanked*, NEW HAVEN REGISTER (New Haven, Conn.), Sept. 16, 1997, at A1; *FDA Pulls Controversial Diet Drugs From Market*, YALE DAILY NEWS (New Haven,

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featured on page one of the *Boston Globe* as well as in other newspapers throughout the area. The *Boston Herald's* article entitled "FDA Warning Sparks Recall of Top Diet Pills" relayed information regarding the withdrawal of diet drugs as well as Wyeth's attempt to contact patients about it.<sup>78</sup> A Boston area television news broadcast further reported that Pondimin and Redux "were touted as miracle drugs for a country obsessed with weight, but health concerns about the diet drugs Fen-Phen and Redux have consumed news reports lately, and yesterday [the date of the withdrawal] the drug makers announced that they are pulling them off the market."<sup>79</sup>

38. The *New York Times* published a front-page article addressing the withdrawal of the diet drugs.<sup>80</sup> The *Buffalo News* also reported that the FDA advised dieters to "immediately stop taking the drugs and see a doctor."<sup>81</sup>

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(WMUR-TV Sept. 15, 1997); *News 9 Night Report* (WMUR-TV Sept. 15, 1997); *5 News Opener* (WCVB-TV television broadcast, Sept. 16, 1997); *7 News Today in New England* (WHDH-TV television broadcast, Sept. 16, 1997); *4 News at 5:00* (WBZ-TV Sept. 16, 1997); *Fox 51 News at 10* (WCSH-TV Sept. 16, 1997); *Newscenter: The Morning Report* (WCSH-TV Sept. 16, 1997); *News 9 Daybreak* (WMUR-TV Sept. 16, 1997); *56 News at 10:00* (WLVI-TV Sept. 17, 1997); *Newsnight* (NECN-TV Sept. 17, 1997); *News 40 at 6:00* (WGGB-TV Sept. 17, 1997); *News 40 at 11:00* (WGGB-TV Sept. 17, 1997); *22 News at 12:00* (WWLP-TV Sept. 17, 1997); *First Look* (NECN-TV Sept. 18, 1997); *Newscenter 5 at 5:00* (WCVB-TV Sept. 19, 1997); *Connecticut News 30 at 9:00* (WVIT-TV Sept. 20, 1997); *Newscenter 5 at 5:00* (WCVB-TV Sept. 22, 1997); *New England Cable News* (NECN-TV Sept. 22, 1997); *News 4 New England* (WBZ-TV Sept. 22, 1997).

<sup>78</sup> Michael Lasalandra, *FDA Warning Sparks Recall of Top Diet Pills*, BOSTON HERALD, Sept. 16, 1997, at 02.

<sup>79</sup> *5 News Opener* (WCVB-TV television broadcast, Sept. 16, 1997).

<sup>80</sup> Gina Kolata, *Companies Recall 2 Top Diet Drugs at FDA's Urging; 'Fen' in Fen-Phen Pulled*, N.Y. TIMES, Sept. 16, 1997, at A1.

<sup>81</sup> Lauran Neergaard, *Recall Spurs Dieters to Seek Heart Tests*, BUFFALO NEWS, Sept. 25, 1997, at A8.